1646

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Keiya Ozawa et al.	Art Unit:	1646
Serial No.:	10/100,471	Examiner:	N. Basi
Filed:	March 18, 2002	Customer No.:	21559
Title:	GENE THAT IMPARTS SELECTIVE PROLIFERATIVE ACTIVITY		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO RESTRICTION REQUIREMENT

In reply to the Restriction Requirement that was mailed in connection with the above-captioned case on March 24, 2005, Applicants elect the invention of Group I, claims 1-8, and elect a ligand-binding domain of an erythropoietin receptor as the species. The election is made with traverse. Claims 1, 2, 6-8, 10, 12, 16-18, and 20-23, as amended in the concurrently filed Preliminary Amendment, read on the elected species. Applicants submit that claims 1, 2, 6-8, 10, 12, 16-18, and 20-23, as amended, should be examined together for the reasons set forth below.

The Restriction Requirement

The Office asserts that the instant application contains claims directed to the following patentably distinct inventions:

- Group I: claims 1-8, directed to fusion proteins, DNA encoding the fusion proteins, and vectors/host cells comprising the DNA;
- Group II: claim 9, directed to a method for selectively proliferating cells expressing fusion proteins;
- Group III: claims 10-18, directed to vectors encoding a desired exogenous gene and a fusion protein;
- Group IV: claim 19, directed to a method for selectively proliferating a cell comprising a vector encoding an exogenous gene and a fusion protein; and
- Group V: claim 20, directed to a kit comprising a vector and a ligand.

Regarding the inventions of Groups I, III, and V, the Office asserts that the claims of these groups are "directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct." Applicants disagree.

The Pending Claims

As an initial matter, as stated in the concurrently filed Preliminary Amendment, claim 1 has been amended to be directed to a fusion protein containing (a) a ligand-binding domain of an erythropoietin receptor that associates when a ligand binds thereto and (b) a domain including a cytokine receptor or a proliferation inducing part thereof that, upon association of the ligand-binding domain, imparts proliferation activity to a cell. Claim 10 has been amended to be directed to a vector containing a desired

exogenous gene and a gene encoding a fusion protein having all of the features of the fusion protein of claim 1.

Claims 3-5, 11, and 13-15 have been canceled. New claims 21-23, which depend from claim 10 and set forth desirable features of the vector, have been added.

Traversal of the Restriction Requirement

Applicants submit that the inventions of Groups I and III, the fusion protein of claims 1 – 8 (now claims 1, 2, and 6-8) and the vector of claims 10 – 18 (now claims 10, 12, 16-18, and 21-23), are related as a subcombination and combination. According to M.P.E.P. (Eighth Edition, Rev. 2, May 2004) § 806.05(c)(II):

> Where the relationship between claims is such that the separately claimed subcombination (B_{sp}) constitutes the essential distinguishing feature of the combination (AB_{sp}) as claimed, the inventions are not distinct and a requirement for restriction must not be made, even though the subcombination has separate utility.

As noted above, the claims have been amended such that all the limitations of the subcombination claim (i.e., the fusion protein of claim 1) are reiterated in the combination claim (i.e., the vector of claim 10). Therefore, restriction between Groups I and III is not proper.

Similar logic applies to Groups III and V. Here, all the limitations of the subcombination claims (i.e., vector of claim 7 or claim 10) are reiterated in the combination claim (i.e., the kit of claim 20). Therefore, restriction between Groups III and V is not proper.

For the above reasons, Groups I, III, and IV (claims 1, 2, 6-8, 10, 12, 16-18, and 20-23) should be rejoined.

Species Election

The Office further asserts that the instant application contains claims directed to patentably distinct species and that claim 1 is generic. In particular, the Office asserts that "numerous structures are possible for the recited fusion proteins." The Office states (page 5):

> Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (i.e., a single sequence or construct) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

Applicants note that the Office fails to set forth a listing of species, one of which Applicants are required to elect. To comply with the election requirement, and to expedite prosecution, Applicants elect a ligand-binding domain of an erythropoietin receptor as the species. As noted above, claims 1, 2, 6-8, 10, 12, 16-18, and 20-23, as amended, read on the elected species.

CONCLUSION

Applicants respectfully request the rejoinder of claims 1, 2, 6-8, 10, 12, 16-18, and 20-23 (Groups I, III, and V). Applicants submit that the application is now in condition for allowance, and this action is hereby respectfully requested.

Enclosed are a Petition to extend the period for replying to the Restriction Requirement for five (5) months, to and including September 26, 2005 (as September 24, 2005 is a Saturday), and a check in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: September 23, 2005

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AMENDMENTS TO THE CLAIMS:

1. (Currently Amended) A fusion protein comprising (a) a ligand-binding domain of an erythropoietin receptor~~, (b) a domain~~ that associates when a ligand binds ~~to~~ thereto ~~the domain of (a)~~, and ~~(c)~~ (b) a domain comprising a cytokine receptor or a proliferation inducing part thereof that, upon association of said ligand-binding domain, imparts proliferation activity to a cell ~~upon the association~~.

2. (Currently Amended) The fusion protein of Claim 1, wherein the [["]]domain comprising a cytokine receptor or a part thereof that imparts proliferation activity to a cell upon the association[["]] is derived from a G-CSF receptor or c-mpl.

3. – 5. (Cancelled)

6. (Original) A DNA encoding the fusion protein of Claim 1.

7. (Original) A vector comprising a DNA of Claim 6.

8. (Original) A cell carrying the vector of Claim 7.

9. (Withdrawn - Currently Amended) A method for selectively proliferating the cell of Claim 8, which comprises exposing the cell of Claim 8 to a ligand capable of acting on the [["]]ligand-binding domain[["]] of the fusion protein of Claim 1.

10. (Currently Amended) A vector comprising a desired exogenous gene and a gene encoding a fusion protein comprising (a) a ligand-binding domain of an erythropoietin receptor~~, (b) a domain~~ that associates when a ligand binds thereto ~~the domain of (a)~~, and ~~(c)~~ (b) a domain comprising a cytokine receptor or proliferation inducing part thereof that, upon association of said ligand-binding domain, imparts proliferation activity to a cell ~~upon the association~~.

11. (Canceled)

12. (Original) The vector of Claim 10, wherein the cytokine receptor is a G-CSF receptor or c-mpl.

13. – 15. (Canceled)

16. (Currently Amended) The vector of Claim 10, wherein the [["]]gene encoding a fusion protein[["]] and the [["]]exogenous gene[["]] are located on the same molecule.

17. (Currently Amended) The vector of Claim 10, wherein the [["]]gene encoding a fusion protein[["]] and the [["]]exogenous gene[["]] are located on separate molecules.

18. (Original) A cell carrying the vector of claim 10.

19. (Withdrawn - Currently Amended) A method for selectively proliferating the cell of Claim 18, which comprises exposing the cell of Claim 18 to a ligand capable of acting on the [["]]ligand-binding domain[["]] of the fusion protein encoded by the gene contained in the vector of Claim 10.

20. (Currently Amended) A kit comprising (a) the vector of Claim 7 or Claim 10, and (b) a ligand capable of acting on the [["]]ligand-binding domain[["]] of the fusion protein encoded by the gene contained in the vector.

21. (New) The vector of claim 10, wherein the exogenous gene encodes a ligand capable of acting on the ligand binding domain.

22. (New) The vector of claim 21, wherein the exogenous gene encodes EPO or TPO.

23. (New) The vector of claim 21, wherein the exogenous gene encodes recombinant human EPO or recombinant human TPO.